In those days, it was very clear who were the regulators and who were the regulated. At that time, validation was still in its infancy and we argued incessantly over the terminology, definitions, and the ever increasing list of acronyms. Ken was working at Pfizer and was also on the program. I can still remember how well he argued his points with the FDA speakers. Ken was always kind in his rebuttal, but never backed down from his position. He didn't so much argue as he explored the issues in a way that was always respectful of the other speakers. I think that is why he was so effective. When...

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